HFI-35 11/29/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

489

Refer to: 1125214

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

November 18, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Louis C. Hoffman, President
Hoffman Orchards, Incorporated
12074 Glen Arm Road
Glen Arm, Maryland 21057

Dear Mr. Hoffman:

During an inspection of your apple cider manufacturing operation, conducted by the Food and Drug Administration from October 8 - 15, 1997, our investigators documented violations of Section 402(a)(4) of the Food, Drug, and Cosmetic Act, and Title 21, Code of Federal Regulations (CFR), Part 110. Significant deviations include the following:

1. Live fruit flies, too numerous to count, were observed throughout the pressroom and bottling room in the plant.

2. Apple pulp was discarded through an open pressroom window, thereby creating a large refuse pile immediately adjacent to the building. During the dumping operation, the reusable press cloths were observed to touch the refuse pile.

3. Doors and windows throughout the plant were open and unscreened, thereby allowing flies, bees, and other insects access to the plant.

4. There were no hand washing or hand sanitizing stations in the plant for the production employees. Production employees were observed handling hoses and equipment and then handling apples without sanitizing their hands.

5. The restroom facilities used by production employees failed to contain toilet paper, hot water, hand soap, or paper towels. In addition, the water supply to the toilet had to be operated by hand to avoid overflow.

6. Apple residue, dirt, and unidentified encrusted material were observed on product contact surfaces, equipment, floors, and walls throughout the processing facility.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Wiley T. Williamson, III, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201. Mr. Williamson can be reached at (410) 962-4366, Extension 136.

Sincerely,

Carl E. Draper
Acting Director, Baltimore District